UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

September 15, 2009

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 63838-1, BioSide HS 5%

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell, PM-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Producer: Enviro Tech Chemical Services, Inc. Div. Brands
500 Winmoore Way
Modesto, CA 95358

Formulation from Label

Active Ingredient(s)	% by wt
Peroxyacetic Acid	5.6 %
Hydrogen Peroxide	26.5 %
Inert Ingredients	67.9 %
Total:	100.0 %

I BACKGROUND

The submitted studies, received April 15, 2009, were conducted by the Ohio Department of Agriculture Microbiology Laboratory as a part of the Antimicrobial Testing Program. On April 14, 2009, the laboratory received one lot of the product BioSide HS 5%. Sample number 09ANAN000002 (lot number 35-8-1230-1) was used to conduct hospital disinfectant testing. The AOAC Use Dilution Method was used to determine the effectiveness of the product against *Staphylococcus aureus* ATCC 6538 and *Pseudomonas aeruginosa* ATCC 15542.

II USE DIRECTIONS

Perasan A is effective against *Staphylococcus aureus*, *Salmonella enterica* (*choleraesuis*), *Pseudomonas aeruginosa, Trichophyton mentagrophytes* and *Escherichia coli* O157:H7 at 2.23%-3% v/v (1.5-20 oz. / 5gal.) in hard water (400 ppm as $CaCO_3$) and 5% organic soil loading on hard non-porous surfaces. For heavily soiled areas, a pre-cleaning step is required, followed by potable water rinse. Apply solution with mop, cloth, sponge, brush, etc... or by soaking or immersion soas to wet well all surfaces thoroughly. Allow treated surfaces to remain wet for 10 minutes, then remove solution and entrapped soil with a clean wet mop, cloth, wet vacuum pickup, or by draining.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Products which are intended for use as broad-spectrum disinfectants labeled for use in hospitals, clinics, dental offices, nursing homes, and any other related institutions must meet the following testing requirements:

(1) **Test standard:** For initial registration, sixty carriers for each of three samples which represent three separate lots, one of which must be at least 60 days old, must be tested against each of the following *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). For the purpose of enforcement testing, only one product lot, instead of the three lots required for initial registration is tested.

(2) **Performance standard:** The product must kill all the test microorganisms on 59 out of each set of 60 carriers/slides to demonstrate effectiveness of the product as a disinfectant.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

The test method used in this assay was that recommended by EPA Guidelines: AOAC Germicidal Spray Products Test (Official Methods of Analysis, Method 961.02). The lab tested the one sample no. 09ANAN000002 for the test. The test method was modified to include the use of 5% horse serum as an organic soil load. The product was diluted 1.5 parts disinfectant in 638.5 parts 400ppm hard water. Testing against was initiated on June 9, 2009 for both microorganisms. All parameters for testing both organisms were the same. The carriers were exposed to the product for a contact time of 10 minutes at 20°C. Letheen broth was used as the neutralizer broth and as the

subculture media. Subculture tubes were incubated at 36+/-1°C for 48-54 hours. All tubes showing positive growth were Gram stained and subcultured on Tryptic Soy Agar and appropriate differential agar plates. Identification of growth was confirmed by Vitek 32 automated system.

V RESULTS

Sample Number	Lot Number	Organism	Carrier Count	No. Positive per Number Tested
09ANAN000002	35-8-1230-1	*Staphylococcus aureus*	4.0×10^6	0/60
09ANAN000002	35-8-1230-1	*Pseudomonas aeruginosa*	1.5×10^7	3/60

VI CONCLUSIONS

1. The submitted data **does not support the effectiveness** of the product Red Lion Research Dis-N-Clean Foaming Disinfectant Cleaner, EPA, Reg. No. 63838-1, as a hospital disinfectant, when tested at 1.5:640 dilution in 400ppm hard water, in the presence of a 5% organic soil load, against ***Pseudomonas aeruginosa*** **(ATCC 15442)** with a contact period of 10 minutes at 20°C.

2. The submitted data does **demonstrate effectiveness** of the product Red Lion Research Dis-N-Clean Foaming Disinfectant Cleaner, EPA, Reg. No. 63838-1, as a hospital disinfectant, when tested at 1.5:640 dilution in 400ppm hard water, in the presence of a 5% organic soil load, against ***Staphylococcus aureus*** **(ATCC 6538)** with a contact period of 10 minutes at 20°C.

3. Since this product is not effective against *Staphylococcus aureus*, it no longer qualifies as a hospital disinfectant. This product should be referred to Regulatory Management Branch I for action.

END